Complete Summary

GUIDELINE TITLE

Midurethral minimally invasive sling procedures for stress urinary incontinence.

BIBLIOGRAPHIC SOURCE(S)

Schulz JA, Chan MC, Farrell SA, Sub-Committee on Urogynaecology. Midurethral minimally invasive sling procedures for stress urinary incontinence. J Obstet Gynaecol Can 2008 Aug;30(8):728-33. [49 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- October 22, 2008 – Surgical mesh devices: The U.S. Food and Drug Administration (FDA) informed healthcare professionals of serious complications associated with transvaginal placement of surgical mesh in repair of pelvic organ prolapse (POP) and stress urinary incontinence (SUI). The FDA provided recommended actions for both physicians and patients to reduce the risks.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Stress urinary incontinence

GUIDELINE CATEGORY

Management

CLINICAL SPECIALTY

Obstetrics and Gynecology
Surgery
Urology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To provide an update on currently used minimally invasive surgical treatments for stress urinary incontinence in women: tension-free vaginal tape (TVT) procedure, transobturator tape (TOT) procedure, and other midurethral sling devices

TARGET POPULATION

Women with stress urinary incontinence

INTERVENTIONS AND PRACTICES CONSIDERED

Midurethral minimally invasive sling procedures for stress incontinence:

- Tension-free vaginal tape (TVT) procedure
- Transobturator tape (TOT) procedure
- TVT SECUR (Gynecare), a new short midurethral sling tape

MAJOR OUTCOMES CONSIDERED

- Cure rates (subjective/objective)
- Complications of surgical procedures

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A search of PubMed and Cochrane library for articles published in English before the end of February 2008 identified the most relevant literature.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Quality of Evidence Assessment*

I: Evidence obtained from at least one properly designed randomized controlled trial.

II-1: Evidence from well-designed controlled trials without randomization.

II-2: Evidence from well-designed cohort (prospective or retrospective) or case–control studies, preferably from more than one center or research group.

II-3: Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results from uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category.

III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

*Adapted from the Evaluation of Evidence criteria described in the Canadian Task Force on Preventive Health Care.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Classification of Recommendations*

A. There is good evidence to recommend the clinical preventive action.
B. There is fair evidence to recommend the clinical preventive action.
C. The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-making.
D. There is fair evidence to recommend against the clinical preventive action.
E. There is good evidence to recommend against the clinical preventive action.

*Adapted from the Classification of Recommendations criteria described in the Canadian Task Force on Preventive Health Care.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This technical update was prepared by the Sub-Committee on Urogynaecology and approved by the Executive of the Society of Obstetricians and Gynaecologists of Canada (SOGC).

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The quality of evidence (**I-III**) and classification of recommendations (**A-E**) are defined at the end of the "Major Recommendations."

1. Tension-free vaginal tape (TVT) can be offered as an alternative of equal efficacy to the Burch procedure for the surgical management of stress urinary incontinence. **(I-A)**
2. Transobturator tape (TOT) can be offered as an alternative to tension-free vaginal tape that eliminates the risks of intra-abdominal organ injury. It should be offered with the proviso that its long-term effectiveness and safety relative to tension-free vaginal tape remain to be determined. **(II-B)**

3. Midurethral sling procedures performed through a single suburethral incision should be used only in the setting of a clinical trial until their effectiveness and safety are proven. **(III-C)**
4. Despite the suggested simplicity of pre-packaged surgical kits for midurethral procedures, specific training is recommended prior to performing any of these surgical procedures. **(III-C)**

Discussion

Since their introduction, minimally invasive midurethral procedures used to treat stress incontinence have been aggressively marketed to surgeons and, in many cases, have supplanted the gold standard Burch procedure. While the evidence now supports the substitution of the TVT procedure for the Burch, it provides very little support for other midurethral procedures. TOT was introduced as a purportedly safer procedure of equal effectiveness to TVT. In considering the rationale for the introduction of TOT it must be remembered that serious retropubic complications from the TVT are rare. While the use of TOT has eliminated the serious retropubic risks, it has introduced a new set of complications. Rates for more minor complications appear to be similar for the two procedures. Therefore, the effectiveness of the procedure should guide selection and patient counselling. TVT has undergone the most rigorous testing; it must therefore be considered superior to the other midurethral procedures until further scientific evidence demonstrates equivalency for another procedure. TOT has demonstrated good short-term results. Other midurethral procedures are currently unsupported by any reliable evidence.

Definitions:

Quality of Evidence Assessment*

I: Evidence obtained from at least one properly designed randomized controlled trial.

II-1: Evidence from well-designed controlled trials without randomization.

II-2: Evidence from well-designed cohort (prospective or retrospective) or case–control studies, preferably from more than one center or research group.

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Classification of Recommendations**

A. There is good evidence to recommend the clinical preventive action.
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D. There is fair evidence to recommend against the clinical preventive action.
E. There is good evidence to recommend against the clinical preventive action.

*The quality of evidence reported in these guidelines has been adapted from the Evaluation of Evidence criteria described in the Canadian Task Force on Preventive Health Care

**Recommendations included in these guidelines have been adapted from the Classification of Recommendations criteria described in the Canadian Task Force on Preventive Health Care.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of midurethral minimally invasive sling procedures for patients with stress urinary incontinence

POTENTIAL HARMS

- Complications with retropubic slings (or tension-free vaginal tape [TVT]) include bleeding, hematoma, erosion of the mesh into the urethra or vagina, bladder perforation, de novo urge symptoms, voiding dysfunction, and infection. Rarer case reports include delayed bowel erosion, bowel injury, bowel obstruction, urethral diverticulum, vesical calculi, paraurethral abscess, necrotizing fasciitis, fistulas, urethral erosions, and nerve damage.
- Complications of transobturator tape (TOT) include postoperative groin pain, risk of damage to the obturator vessel tributary and the vagina, vaginal erosion, and groin abscesses. See also Table 4 in the original guideline document for more TOT complications.

QUALIFYING STATEMENTS

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This document reflects emerging clinical and scientific advances on the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed. Local

institutions can dictate amendments to these opinions. They should be well documented if modified at the local level. None of these contents may be reproduced in any form without prior written permission of the Society of Obstetricians and Gynaecologists of Canada (SOGC).

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Schulz JA, Chan MC, Farrell SA, Sub-Committee on Urogynaecology. Midurethral minimally invasive sling procedures for stress urinary incontinence. J Obstet Gynaecol Can 2008 Aug;30(8):728-33. [49 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2008 Aug

GUIDELINE DEVELOPER(S)

Society of Obstetricians and Gynaecologists of Canada - Medical Specialty Society

SOURCE(S) OF FUNDING

Society of Obstetricians and Gynaecologists of Canada

GUIDELINE COMMITTEE

Sub-Committee on Urogynaecology

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Disclosure statements have been received from all members of the committee.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Society of Obstetricians and Gynaecologists of Canada Web site.

Print copies: Available from the Society of Obstetricians and Gynaecologists of Canada, La société des obstétriciens et gynécologues du Canada (SOGC) 780 promenade Echo Drive Ottawa, ON K1S 5R7 (Canada); Phone: 1-800-561-2416

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on March 18, 2008. The information was verified by the guideline developer on March 25, 2009.

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